

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HAROLD M. HOFFMAN, ESQ.

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ATTORNEY FOR PLAINTIFF

HAROLD M. HOFFMAN, individually and on
behalf of those similarly situated,

Plaintiff,

-against-

PRIMAL FORCE, INC.,

Defendant.

Docket No.: 20-cv-20600 (MCA) (MAH)

**AMENDED COMPLAINT AND
JURY DEMAND IN CLASS ACTION**

Plaintiff *Harold M. Hoffman*, individually and on behalf of those similarly
situated, for his Amended Complaint against Defendant *Primal Force, Inc.*, respectfully
alleges as follows:

INTRODUCTION

This Amended Complaint is filed pursuant to leave of Court for a singular
purpose: to clarify the definition of the class at all times proposed by Plaintiff. (*See*
Order filed 4/22/21). Plaintiff makes no allegation or representation of federal

jurisdiction, and never has, in light of the fact that the consumer class at all times proposed by Plaintiff is specifically limited to New Jersey consumers. Indeed, Defendant has admitted, in writing, that this Court may not exercise jurisdiction over an action defining a class limited to New Jersey purchasers of Defendant's product – precisely the class at all times proposed by Plaintiff in his original pleading, and herein.

Plaintiff brings claims on his own behalf and on behalf of those similarly situated (the "Class"), to redress injury inflicted by Defendant on New Jersey consumers through the manufacturing, advertisement, marketing, distribution and sale of illegal, unapproved drugs.

As detailed below, Defendant, by way of explicit product advertisement directed to New Jersey consumers, including but not limited to advertisements in local newspapers such as the *New York Post*, descriptive literature, and web site claims, promoted, marketed, distributed and sold various products, including but not limited to a purported dietary supplement called ***Primal Max Red***, as effective in, and to be used for, the prevention, cure, mitigation, and therapeutic treatment of disease.

Defendant explicitly claims, represents and promises that Primal Max Red is effective and to be used for, the prevention, cure, mitigation, and therapeutic treatment of Erectile Dysfunction ("ED").

Specifically, Defendant claims that Primal Max Red *contains 5 powerful natural*

nitric oxide boosters that help get large amounts of blood flowing... causing an

erection. Aside from the foregoing bogus claims and misrepresentations that Primal

Max Red treats ED by purportedly increasing blood flow, thereby delivering a harder

and longer erection, and that Primal Max Red is a substitute for a pharmaceutical,

Defendant further claims that Primal Max Red will help the consumer achieve

“increased vigor, strength and mobility,” and that it will “rejuvenate your potency and

power as a man.” According to Defendant, its product “works for as long as you want...

without fizzling out – even for months, or even years, on end.”

Defendant further claims and represents that its product delivers “satisfying

sexual performance,” that its efficacy is evidenced by “clinical trials,” and that it is so

popular, Defendant is having trouble keeping it in stock. Defendant claims and

promises that its product treats loss of erection caused by decreased blood flow, and

that its claims are documented in a “special report.” Finally, Defendant claims and

promises that if “you want passionate, ‘rip your cloths off sex’ that you had in your

younger days,” you must purchase and consume Defendant’s product.

Defendant’s Primal Max Red purportedly contains a formulation of herbs, fruits

and botanicals. Thus, it is a dietary supplement as defined by Congress in the *Dietary*

Supplement Health and Education Act (“DSHEA”) of 1994. A dietary supplement is a

product taken by mouth that contains a “dietary ingredient” intended to supplement the

diet. The "dietary ingredients" in such products may include: vitamins, minerals, herbs or other botanicals, or amino acids. Dietary supplements may be found in many forms such as tablets, capsules, gelcaps, softgels, liquids, or powders.

But, as shown below, the U.S. Food and Drug Administration ("FDA") which enforces the DSHEA, has explicitly ruled that a manufacturer may not lawfully claim that a dietary supplement is therapeutic for disease, including but not limited to ED. Defendant explicitly violates this rule of law.

21 CFR 101.93 [Code of Federal Regulations] specifies the types of descriptive claims that may lawfully be made (and those that are prohibited) with respect to the efficacy of dietary supplements. Subsection (g) of the aforesaid regulation provides that:

Disease claims. (1) For purposes of 21 U.S.C. 343(r)(6), a "disease" is damage to an organ, part, structure, or system of the body such that it does not function properly...

(2) FDA will find that a statement about a product claims to diagnose, mitigate, treat, cure, or prevent disease... under 21 U.S.C. 343(r)(6) if it meets one or more of the criteria listed below...

A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or implicitly, that the product:

(i) Has an effect on a specific disease or class of diseases;

(ii) Has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology;

(iii) Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm.

In interpreting 21 CFR 101.93(g)(2) [above], the FDA has concluded and ruled that a claim that a dietary supplement can treat ED and/or that it can alleviate male potency problems, is a **disease claim**.

Here, Defendant explicitly claims and represents to the consumer that Primal Max Red will treat ED and its symptoms and, that its constituent ingredients are efficacious for male potency problems and ED.

As explicitly held by the FDA, such claims are illicit disease claims. Moreover, Defendant's claims that the concoction of botanicals in Primal Max Red can treat male potency problems and/or ED are bogus. Indeed, such claims are entirely fabricated and constitute material misrepresentations and outright lies.

Defendant makes the foregoing web site, advertising, marketing, promotional literature, and product labeling claims and promises, that not only explicitly violate federal law which prohibits the sale of all unapproved and uncleared products for the mitigation, prevention, treatment, or cure of any disease, they are disingenuous, and bogus. Even were Defendant's claims substantiated by valid medical science (which they are not), dietary supplements, including but not limited to Primal Max Red, may not be sold coupled with therapeutic claims suggesting that they are intended for use in the diagnosis, mitigation, treatment, cure, or prevention of a disease, as this causes them, by operation of federal law, to be considered as **unapproved drugs**.

Defendant's claims and promises with respect to the purported efficacy, therapeutic and monetary value, and legality of Primal Max Red, were calculated and designed to lead members of the class to believe that Primal Max Red was a lawful, appropriate therapy for disease – certainly not an illegal, unapproved drug.

Defendant's claims and promises as aforesaid, constitute material misstatements of fact under the New Jersey *Consumer Fraud Act* and are violative of federal law as Primal Max Red is an unapproved drug that has not been approved by the FDA for its claimed (by Defendant) and purportedly intended purpose. Indeed, even were Defendant's claims and promises not in violation of federal law (which they are), Defendant would nonetheless be guilty of having engaged in an "unlawful practice," in violation of the New Jersey *Consumer Fraud Act*, by virtue of its sale of unapproved drugs and its materially false advertising representations that Primal Max Red constitutes a treatment, therapy, or drug that is efficacious for ED – conduct and practice that stands "outside the norm of reasonable business practice." *See, Turf Lawnmower Repair, Inc. v. Bergen Record Corp.*, 139 N.J. 392, 416 (1995), *cert. denied*, 516 U.S. 1066 (1996). *See also, Van Holt v. Liberty Mut. Fire Ins. Co.*, 163 F.3d 161 (3d Cir. 1998) (lack of full disclosure and honesty constitutes an unconscionable practice under the New Jersey *Consumer Fraud Act*).

The putative class comprises all New Jersey purchasers of Primal Max Red, who

purchased such product during the six year period preceding the filing of this suit.

1. At all times relevant, Plaintiff Harold M. Hoffman had a place of residence in the State of New Jersey, County of Bergen. Plaintiff was exposed to and read, saw and/or heard Defendant's labeling, advertising, web site, and marketing claims and promises in a *New York Post* advertisement of Primal Max Red, and thereafter purchased the product from Defendant in reliance upon such labeling, advertising, web site and marketing claims and promises, in November of 2020, for a purchase price of \$108.90.

2. At all relevant times, Defendant **PRIMAL FORCE, INC.**, was a corporation organized and existing pursuant to the laws of the State of Florida, with its principal place of business located in Royal Palm Beach, FL.

3. In addition to illicit product advertising and labeling of Primal Max Red touting the efficacy of Primal Max Red for disease, Defendant operates a web site wherein it makes and publishes claims and promises with respect to Primal Max Red that are unsubstantiated, bogus, materially false, illegal and in contravention of federal and state law.

4. Defendant advertised, marketed, distributed and sold Primal Max Red in commerce throughout the State of New Jersey, and elsewhere.

5. At all relevant times, plaintiff was and is a consumer, with a residence in the State of New Jersey, County of Bergen.

6. At all relevant times, Defendant constituted a “person” as defined in the New Jersey Consumer Fraud Act, *N.J.S.A. 56:8-1(d)*.

7. For the six-year period preceding the filing of this action, Defendant, through retail and/or other distribution, including *online* distribution and sale, advertised, promoted, marketed, labeled, distributed, and sold Primal Max Red, a purported dietary supplement, as intended to mitigate, prevent, treat or cure disease.

8. According to Defendant’s advertisements, including newspaper advertisements and website claims, promises and representations, and product labeling, Primal Max Red is allegedly comprised of a formulation of herbs and botanicals. Defendant sells its product in powder form.

9. In marketing and selling Primal Max Red to the New Jersey consumer public, Defendant violates explicit FDA laws, rules, regulations and guidelines, as well as the New Jersey *Consumer Fraud Act*, by representing, in its advertising, on its web site, and in promotional literature, that Primal Max Red is a substitute and/or alternative for a pharmaceutical; that it, and/or its constituent ingredients, has a therapeutic effect on disease; and that it is efficacious in the prevention, mitigation,

treatment and cure of disease, including but not limited to ED and its symptoms.

10. In marketing and selling Primal Max Red to the New Jersey consumer public, Defendant further violates explicit FDA laws, rules, regulations and guidelines, as well as the New Jersey *Consumer Fraud Act*, by promising, claiming and representing that its product helps, without limitation, to alleviate male potency problems.

11. Defendant further violates explicit FDA laws, rules, regulations and guidelines, as well as the New Jersey *Consumer Fraud Act*, by claiming that Primal Max Red, and/or its product ingredients belong to a particular class of products (i) intended to cure, treat, prevent, or mitigate disease, and/or; (ii) are suitable as a substitute for a particular pharmaceutical therapy. The claim and promise that Primal Max Red treats ED, and/or that it helps to alleviate male potency problems is materially false, inherently deceptive, as well as unlawful.

12. Based on Defendant's illicit advertising and marketing efforts and product labeling, including the foregoing unlawful claims, Defendant is believed to have sold substantial quantities of Primal Max Red, to consumers throughout the State of New Jersey.

13. Defendant makes the foregoing unlawful claims of product efficacy in its product advertising, on its web sites, through its sales staff, and/or in promotional

literature, which tout, claim and offer Primal Max Red as possessing therapeutic properties capable of preventing, treating and curing disease including but not limited to ED and its symptoms.

14. Primal Max Red, which is touted as a dietary supplement, has not been approved or cleared by the FDA as therapeutic and/or suitable for use in the mitigation, prevention, treatment, or cure of any disease. Thus, Defendant's marketing and sale of Primal Max Red, violates both the New Jersey *Consumer Fraud Act* and the Federal Food, Drug, and Cosmetic Act ("FFDC Act), 21 U.S.C. §§ 331, 343, 352, in that it is an **unapproved and uncleared, new drug** for the diagnosis, mitigation, prevention, treatment, or cure of disease.

15. Primal Max Red is not recognized as safe and effective for the treatment of disease and thus it constitutes a *new drug* under section 201(p) of the FFDC Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed without prior approval from the FDA as described in section 505(a) of the FFDC Act [21 U.S.C. § 355(a)]. The FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective for its claimed and intended purpose. **Defendant has made no such submission to the FDA.** Moreover, the marketing and sale of an unapproved drug constitutes a materially false, unconscionable practice under the New Jersey *Consumer Fraud Act*.

16. Furthermore, Primal Max Red is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for its use cannot be written so that a layperson can use Primal Max Red safely for its purported (albeit bogus), intended purposes. Thus, Primal Max Red is ***misbranded*** within the meaning of section 502(f)(1) of the FFDC Act [21 U.S.C. § 352(f)(1)], in that the labeling fails to bear adequate directions for its use. The introduction of a misbranded drug into interstate commerce is a violation of section 301(a) of the FFDC Act [21 U.S.C. § 331(a)], as well as a violation of the New Jersey *Consumer Fraud Act*.

17. The marketing and sale of misbranded, unapproved or uncleared products, such as Primal Max Red, to treat disease, is a potentially significant threat to the health of New Jersey consumers.

18. Defendant's blatant misrepresentations and false claims regarding the legality and efficacy of Primal Max Red were designed to and did lead class members to believe that they were being lawfully sold and that it was effective (as claimed by Defendant), and conformed to the requirements of federal and state law regulating the marketing of products claiming to treat and/or prevent disease. Members of the Class relied on Defendant's misrepresentations and would not have purchased and/or paid **any** purchase price for an unapproved drug but for Defendant's false claims and

misrepresentations, as well as affirmative concealment of material facts. As a result, Defendant has wrongfully taken substantial sums from hard-working New Jersey consumers.

19. Plaintiff brings this suit to recover funds taken by Defendant as a consequence of its deception of New Jersey consumers through the marketing and sale of illegal, unapproved, new drugs.

20. The affirmative claims, promises and representations made by Defendant in connection with the marketing, advertisement and sale of Primal Max Red, as aforesaid, are false and violative of federal and state law.

21. Members of the putative class are purchasers of Primal Max Red and, prior to purchasing the said product, saw, read and/or heard and relied upon Defendant's advertisements, product labeling, promises, claims and representations, as aforesaid.

22. Members of the class, prior to purchasing the said product, saw, read and/or heard Defendant's promises, product labeling, including website claims and representations as aforesaid, and made an out of pocket payment to Defendant in response thereto and in reliance thereon.

23. The very purpose of the New Jersey Consumer Fraud Act is to protect consumers, such as the putative class members at bar, from being victimized by false and/or illegal promises and claims with respect to product efficacy, value, benefit and legality.

24. In truth and fact, Defendant misrepresented the efficacy, value, legality and benefit of Primal Max Red. Plaintiff and members of the class paid for misrepresented, allegedly therapeutic products that Defendant affirmatively represented to be lawful and effective in the mitigation, treatment and cure of disease, as aforesaid.

25. New Jersey consumers made purchasing decisions and did, in fact, make purchases from Defendant based upon Defendant's specific claims and representations of product efficacy, value, legality and benefit for a claimed, therapeutic purpose.

26. Defendant has affirmatively misrepresented, misbranded and mislabeled Primal Max Red.

27. The affirmative promises and representations made by Defendant – both in product labeling and in marketing and web site advertisements and representations – in connection with Primal Max Red, are false, illegal and misleading. Members of the class were entitled to trust the Defendant's labeling and marketing representations and

advertisements with respect to its product. The product delivered by Defendant to members of the putative class was materially misrepresented.

28. Defendant's advertisements, promises and representations concerning Primal Max Red, are illegal, false and constitute a deception; a misrepresentation; an unconscionable trade practice; a sharp and deceitful marketplace practice, and are a false promise.

29. Defendant's advertisements, promises and representations concerning Primal Max Red result in New Jersey consumers who purchased the product, being subjected to misrepresentation, false promise, fraud, deceit, trickery and false and deceptive advertising.

30. Defendant has made affirmative misrepresentations and has engaged in concealment of material facts in connection with the sale, marketing and/or advertisement of Primal Max Red, and to induce its sale.

31. Members of the putative class suffered ascertainable loss in the form of actual out of pocket payment and expenditure, as aforesaid, as a result of Defendants' unlawful conduct as aforesaid. Members of the putative class paid hard earned money and received from Defendant, in exchange, **unapproved, new drugs** that have no therapeutic effect and/or value, and which were marketed and sold in violation of

governing federal and state law. Indeed, there was a substantial difference between the price paid by consumers, including plaintiff and class members, for the Defendant's product, and the represented value of the product. Here, for their money, members of the Class received illegal, unapproved and useless drugs. Thus, members of the Class did not receive the "benefit of their bargain."

32. Plaintiff and members of the class also suffered ascertainable loss when they received, for their money, illegal, unapproved drugs which constitute over-priced products that are objectively less than, inferior to, and different from, the product promised by Defendant. The Defendant's product failed to measure up to the consumers' reasonable expectations based on the representations made by Defendant. Thus, purchasers of said products were injured and suffered loss.

33. For their money, members of the class received something less than, and different from, what they reasonably expected in view of Defendant's representations. Indeed, consumers did not anticipate purchasing useless, unapproved drugs – a fact material to the transaction that was affirmatively concealed and/or misrepresented by Defendant. As a result, consumers suffered ascertainable loss.

34. Defendant marketed and sold Primal Max Red - and consumers purchased it - on the premise that the said product was being lawfully sold to deliver

specified benefit. Thus, there is a causal relationship between the Defendant's misrepresentations of lawful efficacy and the loss suffered by plaintiff and class members.

CLASS ALLEGATIONS

35. Plaintiff brings this suit as a class action individually and in behalf of others similarly situated. Subject to additional information obtained through further investigation and/or discovery, the definition of the Class may be expanded or narrowed. The proposed Class consists of all New Jersey (and only New Jersey) purchasers of Primal Max Red, who purchased such product during the six year period preceding the filing of this suit.

Numerosity: The members of the Class are so numerous that joinder of all members is impracticable. The Class is comprised of consumers throughout the State of New Jersey.

Commonality: Common questions of law and fact exist as to all members of the Class. These common questions predominate over the questions affecting only individual Class members, and include:

- a. Whether Defendant made affirmative misrepresentations in violation of the New Jersey Consumer Fraud Act;
- b. Whether Defendant marketed Primal Max Red in violation of federal law; and,

- c. The appropriate measure of damages sustained by the Plaintiff and/or other members of the Class.

Typicality: Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct. Plaintiff, like other members of the Class, purchased and consumed Primal Max Red, after exposure to the same misrepresentations and/or omissions in Defendants' advertising and received a product less than and different from the promised product. Plaintiff is advancing claims and legal theories typical to the Class.

Adequacy: Plaintiff's claims are made in a representative capacity on behalf of all members of the Class. Plaintiff has no interests antagonistic to the interests of the other members of the proposed Class and is subject to no unique defenses.

36. Plaintiff is similarly situated in interest to all members of the proposed Class and is committed to the vigorous prosecution of this action. Accordingly, Plaintiff is an adequate representative of the proposed Class and will fairly and adequately protect the interests of the Class. Plaintiff is also an experienced attorney who has been previously appointed class counsel for certified classes of consumers by both state and federal courts. Thus, Plaintiff is a qualified and suitable attorney to also serve as class

counsel. Should the Court require same as a condition to class certification, Plaintiff is prepared to identify a suitable alternative class representative.

37. This suit may be maintained as a class action because Defendant has acted, and/or have refused to act, on grounds generally applicable to the Class, thereby making final relief appropriate.

38. Plaintiff does not presently seek injunctive relief.

39. **Superiority:** In addition, this suit may be maintained as a class action because a class action is superior to all other available methods for the fair and efficient adjudication of this controversy, since joinder of all members is impracticable. The claims asserted herein are applicable to all consumers throughout the State of New Jersey who purchased Primal Max Red. The injury suffered by each individual class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendant's conduct. It would be virtually impossible for members of the Class individually effectively and cost-efficiently to redress Defendant's wrongful conduct. Individual litigation would enhance delay and expense to all parties. The class action device presents far fewer management difficulties, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

COUNT I

40. Plaintiff repeats and realleges the prior allegations of this complaint as if fully set forth at length.

41. Defendant's conduct constitutes an unconscionable commercial practice in violation of the New Jersey Consumer Fraud Act, *N.J.S.A.* 56:8-2.

42. As a proximate result of Defendant's conduct, plaintiff and members of the class were damaged.

WHEREFORE, plaintiff, individually and in behalf of the class, demands judgment against the Defendant for treble damages together with pre-judgment and post-judgment interest, fees, costs, attorney's fees, civil penalties mandated by *N.J.S.A.* 56:8-19, and any other and further relief as the Court deems just and proper.

COUNT II

43. Plaintiff repeats and realleges the prior allegations of this complaint as if fully set forth at length.

44. Defendant's conduct constitutes deception in violation of the New Jersey Consumer Fraud Act, *N.J.S.A.* 56:8-2.

45. As a proximate result of Defendant's conduct, plaintiff and members of the class were damaged.

WHEREFORE, plaintiff, individually and in behalf of the class, demands judgment against the Defendant for treble damages together with pre-judgment and post-judgment interest, fees, costs, attorney's fees, civil penalties mandated by *N.J.S.A.* 56:8-19, and any other and further relief as the Court deems just and proper.

COUNT III

46. Plaintiff repeats and realleges the prior allegations of this complaint as if fully set forth at length.

47. Defendant's conduct constitutes fraud in violation of the New Jersey Consumer Fraud Act, *N.J.S.A.* 56:8-2.

48. As a proximate result of Defendant's conduct, plaintiff and members of the class were damaged.

WHEREFORE, plaintiff, individually and in behalf of the class, demands judgment against the Defendant for treble damages together with pre-judgment and post-judgment interest, fees, costs, attorney's fees, civil penalties mandated by *N.J.S.A.* 56:8-19, and any other and further relief as the Court deems just and proper.

COUNT IV

49. Plaintiff repeats and realleges the prior allegations of this complaint as if fully set forth at length.

50. Defendant's conduct constitutes false pretense, false promise and/or misrepresentation, in violation of the New Jersey Consumer Fraud Act, *N.J.S.A. 56:8-2*.

51. As a proximate result of Defendant's conduct, plaintiff and members of the class were damaged.

WHEREFORE, plaintiff, individually and in behalf of the class, demands judgment against the Defendant for treble damages together with pre-judgment and post-judgment interest, fees, costs, attorney's fees, civil penalties mandated by *N.J.S.A. 56:8-19*, and any other and further relief as the Court deems just and proper.

COUNT V

52. Plaintiff repeats and realleges the prior allegations of this complaint as if fully set forth at length.

53. Defendant's conduct constitutes knowing concealment, suppression and/or omission of material facts with the intent that others, including members of the plaintiff-class, rely upon such concealment, suppression and/or omission, in connection with the sale or advertisement of any merchandise in violation of the New Jersey Consumer Fraud Act, *N.J.S.A. 56:8-2*.

54. As a proximate result of Defendant's conduct, plaintiff and members of the class were damaged.

JURY DEMAND

Demand is hereby made for trial by jury as to all issues.

WHEREFORE, plaintiff, individually and in behalf of the class, demands judgment against the Defendant for treble damages together with pre-judgment and post-judgment interest, fees, costs, attorney's fees, civil penalties mandated by N.J.S.A. 56:8-19, and any other and further relief as the Court deems just and proper.

Dated: May 3, 2021

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